(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use.* It is used in dogs, cats, and horses as follows:

(1) *Amount. Dogs*: 0.25 to 0.5 mg per pound (/lb) of body weight; Cats: 0.5 to 1.0 mg/lb of body weight; Horses: 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* As a tranquilizer.

(e) *Conditions of use.* It is used in dogs as follows:

(1) *Amount. Dogs*: 0.25 to 0.5 mg/lb of body weight.

(2) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

[75 FR 10167, Mar. 5, 2010]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.[1]

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.[1]

(3) For use only by or on the order of a licensed veterinarian.[1]

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(c) *Conditions of use.* It is used in horses as follows:

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17338, Mar. 29, 2011]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the

treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use dosage may be continued by oral administration of tablets.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) *Specifications.* Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis in cats and dogs and in colic spasms in horses.[1]

(2) It is administered intramuscularly or intravenously to dogs and cats at a level of 1 to 2 milligrams per pound of body weight. It is administered intramuscularly or intravenously to horses at a level of 0.25 milligrams per pound of body weight. Dosage can be repeated every 12 hours, as indicated.[1]

[1]These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(3) Not for use in animals intended for food purposes.[1]

(4) For use only by or on the order of a licensed veterinarian.[1]

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.84 Beta-aminopropionitrile fumarate.

(a) *Specifications.* Each vial contains 7.0 milligrams of beta-aminopropionitrile fumarate sterile lyophilized powder which is reconstituted for injection with 10 milliliters of sterile physiologic saline, USP.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 7 milligrams (10 milliliters) intralesionally every other day for 5 treatments beginning about 30 days after initial injury.

(ii) *Indications for use.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing.

(iii) *Limitations.* Single dose container for intralesional injection. Do not use in horses with dermal irritation or open skin lesions in the injection area. Do not administer intraarticularly, into the tendon sheath, or in the presence of concurrent limb fractures. Do not use in breeding animals since the effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44382, Aug. 19, 1998]

§ 522.88 Sterile amoxicillin trihydrate for suspension.

(a)(1) *Specifications.* Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of